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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,186	03/06/2002	Alexandru R. Moise	UBC-0002	8609

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EXAMINER

ANGELL, JON E

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/009,186

Applicant(s)

MOISE ET AL.

Examiner

Jon Eric Angell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-17 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Claims 1-17 are currently pending and are addressed herein.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 4, 5, 6, 12 drawn to a method for inhibiting apoptosis in a cell comprising administering to the cell an effective amount of a E3/6.7K polypeptide.

Should Group I be elected, further election of one of the following patently distinct subgroups should also be elected. To be clear, the subgroups listed below are not species, but are independent inventions which do not have unity of invention.

Group I wherein the method is comprises:

- i) in vitro treatment
- ii) ex vivo treatment
- iii) in vivo treatment

Should Group I, i-iii be elected, further election of one of the following patently distinct subgroups should also be elected. To be clear, the subgroups listed below are not species, but are independent inventions which do not have unity of invention.

Group I, wherein the cell is in a patient suffering from:

- a) a degenerative disease
- b) an immunodeficiency disease
- c) an inflammatory disease
- d) a neurodegenerative disease

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Group II, claim(s) 2-5, 7, 12 drawn to a method for inhibiting apoptosis in a cell comprising administering to the cell an effective amount of a nucleic acid encoding a E3/6.7K polypeptide.

Should Group II be elected, further election of one of the following patently distinct subgroups should also be elected. To be clear, the subgroups listed below are not species, but are independent inventions which do not have unity of invention.

Group II wherein the method is comprises:

- i) in vitro treatment
- ii) ex vivo treatment
- iii) in vivo treatment

Should Group II, i-iii be elected, further election of one of the following patently distinct subgroups should also be elected. To be clear, the subgroups listed below are not species, but are independent inventions which do not have unity of invention.

Group II, wherein the cell is in a patient suffering from:

- a) a degenerative disease
- b) an immunodeficiency disease
- c) an inflammatory disease
- d) a neurodegenerative disease

Group III, claim(s) 8, drawn to a pharmaceutical composition comprising a E3/6.7K polypeptide.

Group IV, claim(s) 9-11, drawn to a nucleic acid comprising a non-naturally occurring adenovirus E3 nucleic acid capable of encoding a E3/6.7K polypeptide.

Group V, claim(s) 13, drawn to the use of an E3/6.7K polypeptide for the preparation of a medicament.

Group VI, claim(s) 13, drawn to the use of a nucleic acid encoding E3/6.7K polypeptide or a vector comprising said nucleic acid for the preparation of a medicament.

Group VII, claim(s) 14-17, drawn to an assay for an agent that modulates anti-apoptotic activity of a E3/6.7K polypeptide.

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Therefore, applicants must elect one (1) of the following Groups:

I, i, a
I, i, b
I, i, c
I, i, d
I, ii, a
I, ii, b
I, ii, c
I, ii, d
I, iii, a
I, iii, b
I, iii, c
I, iii, d
II, i, a
II, i, b
II, i, c
II, i, d
II, ii, a
II, ii, b
II, ii, c
II, ii, d
II, iii, a
II, iii, b
II, iii, c
II, iii, d
III
IV
V
VI
VII

37 CFR 1.475(b) states:

“An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or

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- (2) A product and process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) A process and an apparatus or means specifically designed for carrying out the said process; or
- (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

37 CFR 1.475(c) states:

“If an application contains claims to more or less than one of the combination of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.”

37 CFR 1.475(d) also states:

“If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and 1.476(c).”

37 CFR 1.475(e) further states:

“The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternative within a single claim.”

The inventions listed as Groups I-V including (I, i-iii, a-d and II, i-iii, a-d) do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2,

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they lack the same or corresponding special technical features for the following reasons: there is no special technical feature linking the Groups because in order for a technical feature to be considered "special" it must be novel. In the instant case the technical feature linking the claims is E3/6.7K. Since E3/6.7K was known in the prior art, as indicated in the International Search Report (ISR) (e.g., see WO 99 08310 A, WO 99 02658 A, LIPPE, ELSING, WILSON-RAWLS (1) and WILSON-RAWLS (2) references cited in the ISR) it is not novel, and, as such, there is no special technical feature linking the Groups. Furthermore, the different methods are unique methods of treatment that pertain to treating different diseases by different method steps. As such, treating each specific disease (e.g., degenerative, immunodeficiency, inflammatory, and neurodegenerative diseases) comprises treating a different disease wherein each disease has different symptoms, effects, causes, etc. Furthermore, in vitro, ex vivo and in vivo treatments all have different method steps and considerations.

It is noted that the claims include claims that have improper dependency. For example, claim 1 is clearly drawn to a protein therapy, while claim 2 (which depends on claim 1) is clearly drawn to nucleic acid therapy. Therefore, claim 2 improperly depends on claim 1 and should be re-written in response to this action such that the improper dependency is removed.

A telephone call was made to Jeffrey King on 8/17/04 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).


Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon Eric Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Mon-Fri, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


DAVE T. NGUYEN
PRIMARY EXAMINER

Jon Eric Angell, Ph.D.
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